



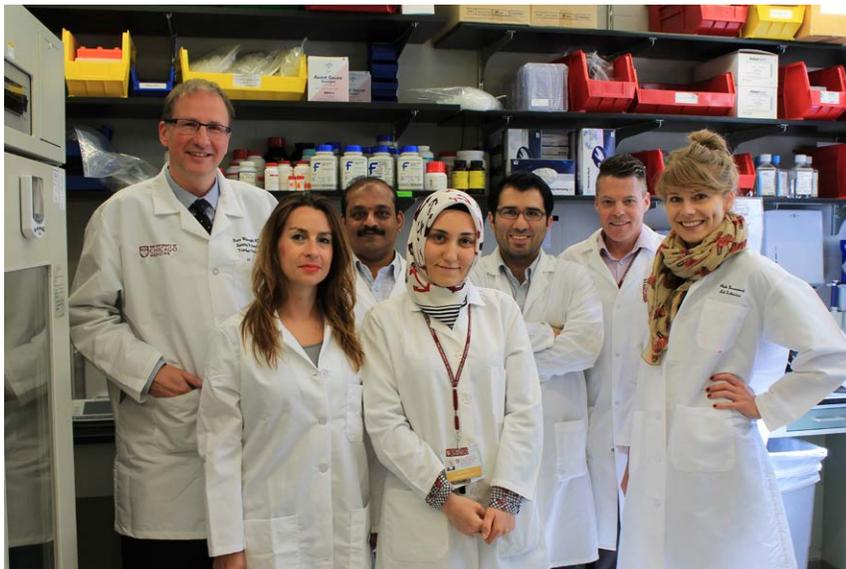
# ACTS ASSOCIATION FOR CLINICAL AND TRANSLATIONAL SCIENCE

# Connection

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## University of Chicago Institute of Translational Medicine Pilot Awardee Update

*March 2015*



Between 14 and 22 million people in the United States suffer from autoimmune diseases, such as type 1 diabetes, multiple sclerosis, and rheumatoid arthritis, according to the National Institutes of Health (NIH), with the medical cost of treating type 1 diabetes and multiple sclerosis alone topping more than \$7 billion each year.

But with the help of an ITM Pilot Award, Piotr Witkowski, MD, PhD, is one step closer to curing those conditions – and ending the body's rejection of organ transplants.

In November 2010, Witkowski and his team initiated the development and optimization of expanding the number of regulatory T cells (Tregs) outside the body in his laboratory.

Additional details about the progress of this research can be found on the [ITM website](#).

*This article was written by and reprinted with permission from Sara Serritella.*

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## Join Geoffrey Smith, JD and Other Notable Plenary Speakers at Translational Science 2015

Translational Science 2015 is less than a month away! Join us April 16 -18 at the Omni Shoreham for the meeting that brings together a multidisciplinary audience of clinical and translational researchers, for the unique benefit of networking and education with leaders.

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### About ACTS

The ACTS mission is to advance research and education in clinical and translational science to improve human health. For more information, visit [actscience.org](http://actscience.org)

### The Association for Clinical and Translational Science

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Translational Science 2015 is offering [four plenary sessions](#) featuring six plenary speakers designed to reach everyone from trainees to senior investigators. Among the plenary speeches includes:

**Scaling & Entrepreneurship**, presented by Geoffrey Smith, JD, Managing Director, Mars Grand Challenge Ventures

*Entrepreneurs work hard to scale initial ideas into thriving enterprises. How important is scale in achieving success? Do the laws of scaling observed in biology and social networks provide any lessons for entrepreneurs? This talk will explore various paths to entrepreneurial success.*

[Register Now!](#)

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## [Hotel Rooms for Translational Science 2015 Now Available at the Marriott Wardman Park](#)

Due to overwhelming demand, the discounted room rate at the Omni Shoreham is no longer available. You can still book rooms at the non-conference rate. If you would like to make a reservation by phone, please call (202) 234-0700.

We have reserved additional rooms at a discounted conference rate at the Washington Marriott Wardman Park. Rooms are on a first-come, first-served basis. Please call 1-202-328-2000 or visit the [Marriott Wardman Park website](#) to book your room.

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## [From the Hill--ACTS Advocacy News](#)

Congress returned from a brief recess and took up a number of issues related to medical research and patient care. The actions legislators take now will set up legislative and policy efforts that will culminate later this year.

- House Republicans released a non-binding budget proposal, A Balanced Budget for A Stronger America. While merely a blueprint outlining priorities, the proposal calls for spending reductions of \$5.5 trillion over the next 10 years.
- At a recent event on Capitol Hill advocating for cancer research funding, Congressmen Matt Salmon (R-AZ-5th) and Kevin Yoder (R-KS-3rd) called for specific and meaningful funding increases for the National Institutes of Health (NIH).
- Legislators continue working to prepare a permanent overhaul of the sustainable growth rate system to improve Medicare physician reimbursement.

Visit the [ACTS website](#) to read additional details about these legislative actions. If you would like to know more about specific legislative and policy issues impacting the clinical and translational research community, please [become an advocate](#), join the monthly advocacy call, or [participate in Hill Day](#).

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## [FDA Draft Guidance, Consent in Clinical Investigation](#)

The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry, clinical investigators, and institutional review boards entitled 'Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers.' The guidance provides recommendations for clinical investigators, sponsors, and institutional review boards (IRBs) on the use of electronic media and processes to obtain informed consent for FDA-regulated clinical investigations of medical products, including human drug and

biological products, medical devices, and combinations thereof. Although you can comment on any guidance at any time, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 8, 2015.

Get additional details on how to submit your comments on the [ACTS website](#).

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## News from ACTS

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Share your exciting stories...Membership News!

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## News from ACTS

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Share your exciting stories...Membership News!

Does your institution have news you want to share with the *ACTS Connection* readership? Do you have an investigator doing something innovative? Let us know! From innovative projects, star scholars and trainees, to award winning faculty, help us share the news that is important to you by submitting it through our [online form](#).

Your news may be shared on the ACTS website, and other ACTS social media sources!

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## Translational Science News

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### Thousands Have Already Signed Up for Apple's ResearchKit

Less than 24 hours after Apple's ResearchKit was introduced, 11,000 people had already used the iPhone tool to sign up for a cardiovascular study, Stanford University researchers report. Getting that many people in a medical study usually takes a year and 50 medical centers, according to Alan Yeung, medical director of Stanford Cardiovascular Health. Stanford researchers are using ResearchKit to study ways to encourage people to modify their behavior to improve cardiovascular health. Find out more about Apple's ResearchKit [here](#).

From "Thousands Have Already Signed Up for Apple's ResearchKit"  
*Bloomberg (03/11/15) Cortez, Michelle Fay; Chen, Caroline*

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### Compliance With Results Reporting at ClinicalTrials.gov

Under the FDA Amendments Act (FDAAA), applicable clinical trials must be reported to ClinicalTrials.gov in a timely manner. Duke University researchers examined applicable clinical trials to find factors associated with the reporting of results. From ClinicalTrials.gov, investigators identified 13,327 trials that were

likely to be subject to FDAAA provisions from 2008-2013. Here's what they found:  
[Compliance with Results Reporting at ClinicalTrials.gov](#)

From "Compliance With Results Reporting at ClinicalTrials.gov"  
*New England Journal of Medicine (03/12/15) Vol. 372, No. 11, P. 1031 Anderson, Monique L.; Chiswell, Karen; Peterson, Eric D.; et al.*

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### **Lack of Standard Data Model Poses Hindrance to PCORI 'Network of Networks'**

The development of a "network of networks" to help the progress of comparative effectiveness research (CER) could experience setbacks due to a lack of a standard data model, the Government Accountability Office (GAO) reports. The Patient-Centered Outcomes Research Institute has set priorities and process for funding CER, awarding 360 contracts as of October 2014. The planned National Patient-Centered Clinical Research Network (PCORnet), however, could see a variety of hindrances.

From "Lack of Standard Data Model Poses Hindrance to PCORI 'Network of Networks'"  
*Fierce HealthIT (03/11/15) Hall, Susan D.*

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### **Dementia Drug Research Aided by \$100 Million Venture Capital Fund**

Dementia Discovery Fund, the world's first venture capital fund dedicated to the prevention and treatment of dementia, has raised more than \$100 million with the backing of the U.K. government and several leading pharmaceutical companies. A Group of Eight (G8) nation's conference in London in December 2013 set a goal of finding a cure or effective treatment for dementia by 2025, a goal that could be aided by pooling resources through the new fund.

From "Dementia Drug Research Aided by \$100 Million Venture Capital Fund"  
*Reuters (03/17/15) Hirschler, Ben*

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## **Grant Opportunities**

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### **John Merck Fund Developmental Disabilities Translational Research Program**

The John Merck Fund is accepting applications for the Developmental Disabilities Translational Research Program. The program, launched in 2012, provides support for researchers in developing treatments and improving outcomes for people with developmental disabilities. The Fund is seeking highly innovative translational research projects that have the greatest potential of investigating rational and effective treatments and interventions for the particular condition being studied. Interdisciplinary collaborative grant applications that focus primarily on Down syndrome and Fragile X syndrome are the emphasis; however, the program also supports studies focused on other developmental disabilities under special circumstances. Of particular interest is translational research that is designed to enhance the lives of people with developmental disabilities and their families. Scientists at any career stage with a scholarly commitment to developmental disabilities are eligible to apply. The program will make about 10 awards of \$1 million each over the spendout period. Preliminary proposals are due by May 18, 2015.

From "John Merck Fund Developmental Disabilities Translational Research Program"

*John Merck Fund (03/26/15)*

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### **DoD Ovarian Cancer Clinical Translational Award**

The U.S. Department of Defense has announced the DoD Ovarian Cancer Clinical Translational Award. The award aims to support translational research addressing high-impact ideas or unmet needs in ovarian cancer. This award mechanism support preclinical and clinical research studies; clinical trials are not supported. The award can also be used to support research projects associated with ongoing

or completed clinical trials supported by other funding sources. Estimated total program funding is \$1.44 million. The deadline for applications is August 5, 2015.

From "DoD Ovarian Cancer Clinical Translational Award"  
*Grants.gov (03/23/15)*

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### **Limited Competition: Revisions to Add Phase 2 Clinical Trials Program to Experimental Therapeutics Clinical Trials Network (ETCTN)(UM1)**

The National Institutes of Health (NIH) has issued a funding opportunity announcement to enhance the National Cancer Institute-supported early development of experimental cancer therapeutics by merging the Phase 2 clinical trials program with the Experimental Therapeutics Clinical Trials Network (ETCTN, funded through RFA-CA-13-006) that is currently focused on Phase 1 clinical trials. NIH is seeking revision applications from ETCTN UM1 awardees to increase the scope of activities by adding capabilities for Phase 2 clinical trials. Integrating the Phase 2 capabilities into the new ETCTN structure will enable more seamless advancement of experimental agents through early stages of development. The estimated total project funding is \$7.2 million, with an award limit of \$560,000. The deadline for applications is June 19, 2015.

From "Limited Competition: Revisions to Add Phase 2 Clinical Trials Program to Experimental Therapeutics Clinical Trials Network (ETCTN)(UM1)"  
*Grants.gov (03/23/15)*

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### **NIMH Research Education Mentoring Program for HIV/AIDS Researchers (R25)**

The National Institutes of Mental Health (NIMH) has issued a funding opportunity announcement for the NIMH Research Education Mentoring Program for HIV/AIDS Researchers (R25). The program aims to support educational activities that complement and/or enhance the training of a workforce to meet the nation's biomedical, behavioral, and clinical research needs and advance the priorities outlined in the Office of AIDS Research Annual Strategic Plan and the research program priorities of the NIMH Division of AIDS Research. The funding will support creative educational activities with a primary focus on mentoring activities and research experiences that build on existing networks of collaborating investigators or develop institute-based research education program. Applicants may seek budgets of up to \$250,000 in direct costs annually for projects not to exceed five years in length. Applications are due by Sept. 7, 2015.

From "NIMH Research Education Mentoring Program for HIV/AIDS Researchers (R25)"  
*NIH Grants (03/19/15)*

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### **NHLBI SBIR Phase IIB Bridge Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (R44)**

The National Heart, Lung, and Blood Institute (NHLBI) has issued a funding opportunity announcement for NHLBI SBIR Phase IIB Bridge Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (R44). The awards aim to facilitate and accelerate the steps that are required to transition SBIR/STTR Phase II projects to the commercialization stage by promoting partnerships between SBIR/STTR Phase II awardees and third-party investors and/or strategic partners. Applicants must submit a Commercialization Plan, including details on any independent third-party funding that has already been secured or is anticipated during the Phase IIB Bridge Award project period. Budgets of up to \$3 million in total costs may be requested for projects lasting up to three years. The application deadline is June 19, 2015.

From "NHLBI SBIR Phase IIB Bridge Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (R44)"  
*NIH Grants (03/05/15)*

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### **William T. Grant Foundation Research Grants**

The William T. Grant Foundation is inviting applications for its research grants. The foundation invests in research with the potential to advance theory, policy, and practice related to children and adolescents in the United States, and its program supports theory-building and empirical research projects on reducing inequality or understanding the use of research evidence. The research grants typically range from \$100,000 to \$600,000 and cover two to three years of support. Letters of inquiry for this round of funding are due by May 5, 2015.

From "William T. Grant Foundation Research Grants"  
*William T. Grant Foundation (03/12/15)*

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